VERISTAT™

Fact sheet

High Quality, On Time Submissions

Ensuring success across NDA, BLA, and MAA

Get your submission right the first time

Consolidating the scientific and regulatory information required to support a submission for marketing approval is a critical step for any drug development program. Many teams struggle with setting and adhering to a timeline for planning, drafting, reviewing, and editing the regulatory documents needed for the submission dossier.

Veristat offers tailored, end-to-end submission preparation support, from high-level strategy to getting the submission done. Whether planning and writing the dossier (Modules 1–5), regulatory consulting for pre-submission health authority interactions, biostatistics support for pooling and datasets, or Regulatory Operations for publishing and transmission, Veristat has the expertise to support every step of your submission journey.

A fully integrated, end-to-end offering tailored to your needs

Regulatory Consulting

- Pre-submission meetings with Health Authorities
- Accelerated pathway requests
- Overall messaging support

Regulatory Writing

- Pre-submission meeting requests and briefing documents
- CMC, Nonclinical and Clinical Summary documents
- ISS/ISE/ISI summaries
- SME review and Quality Control
- Regulatory responses during Health Authority review
- Lay Summary writing

Submission Leadership

- Team leadership and Project Management
- Pooling strategy and strategic timeline development
- Labeling and key messaging support

Biostatistics and Programming

- CDISC-compliant SDTM, AdAM, and Bioresearch Monitoring (BIMO)datasets
- Saps, analyses, and outputs for ISS/ISE/ISI preparation
- SEND datasets for Nonclinical Studies
- Post-submission Agency information requests

Regulatory Operations

- Marketing application and investigational and master file submissions
- Lifecycle maintenance submissions
- US Agent services

Additional Services

- Publication planning
- Transparency and disclosure services
- Public release of marketing applications
- Document quality control, templates, and style guides

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Why Veristat?

The value of unmatched scientific expertise and wide-ranging drug development experience

Experience

More than 93% of the nearly 400 regulatory submissions delivered by Veristat have been approved.

Quality

In the past 5 years, Veristat has delivered 230+ regulatory submissions with 100% on-time delivery.

Accelerated Pathways

Experience with Accelerated, Emergency Use Authorization, Fast-track, PRIME, and Breakthrough Therapy Designations.

Rare/Orphan Disease

Extensive experience on over 120 submissions in the past 5 years.

Global Submissions

Veristat supports parallel submissions across all major global markets, from strategy to delivery.

Submission Partnership

Veristat partners with your team, whether supporting a large global organization or guiding a lean biotech through its first submission.

Veristat Regulatory Leaders

Steve Sibley
VP, Global Submissions & Submission Leadership

Mark McBride
VP, Global Biostatistics and Programming

See how smart planning streamlines submission

Watch the webinar to explore essential regulatory writing and operations strategies

About Veristat: a Partner Who Shares Your Commitment to Success

Veristat, the full service CRO and consultancy, integrates strategic planning, regulatory strategy, and clinical trial execution to rapidly advance the most complex or novel therapies.
At Veristat, we are problem-solvers. Scientific experts. Regulatory upholders. We engage with clients collaboratively to support their delivery of life-changing therapies and are equipped to take the lead on any development and commercialization program. With our focus on novel drug development and 30 years of experience in clinical trial planning and execution, we deliver bold approaches that make the impossible possible.

Ready to meet Veristat? Let's Talk.

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